



Mr. Robert C. Gelardi  
Lyn O'Brien Nabors  
Calorie Control Council  
5775 Peachtree-Dunwoody Road  
Suite 500-G  
Atlanta, Georgia 30342

Dear Mr. Gelardi and Ms. Nabors:

This letter responds to your letter of February 11, 1999, pertaining to the use of the term "polyol" in nutrition labeling as you addressed in a citizen's petition dated April 4, 1995 (Docket No. 95P-0099/CP1). It also responds to your two letters of March 15, 1999, one pertaining to the use of a value of not more than 2 calories per gram for soluble dietary fiber addressed in a citizen's petition dated February 13, 1997 (Docket No. 97P-0056/CP1), and the other pertaining to the removal or reduction of an ingredient from a standardized food addressed in two citizen's petitions dated March 13, 1995 and May 3, 1996 (Docket Nos. 95P-0078 and 96P-1043/CP1, respectively).

This is to advise you that we do not agree that the term "polyol" can be used in the nutrition facts panel in lieu of the term "sugar alcohol" prior to our reaching a decision on the petition you have submitted. As you are aware, the regulations governing food labeling (see 21 CFR 101.9(c)(6)(iii)) currently require use of the term "sugar alcohol" in the nutrition facts panel when a claim is made about sugars or sugar alcohols and sugar alcohols are present in the food. By way of exception, if only one sugar alcohol is present in the food, the name of the specific sugar alcohol may be listed (e.g., "xylitol"). This same regulation provides that the term "sugar alcohol" may be used voluntarily in the nutrition facts panel to declare the amount of sugar alcohols present in a food. Any change in the regulation would require notice-and-comment rulemaking. Therefore, we would have an objection to the Calorie Control Council advising its members to use the term "polyols" in place of the term "sugar alcohols" in the nutrition facts panel, as requested in your letter of February 11, 1999.

Likewise, we do not agree that a food factor of 2 may be used for calculating the caloric value of soluble fibers prior to the Center's full review of your petition. In addition to the question raised in your petition about the caloric contribution of fiber, questions also remain about the definition of dietary fiber, in general, and more specifically about the definition of soluble fiber. Again, the action you are requesting requires notice-and-comment rulemaking, in this case to amend §101.9(c)(1)(i) that requires the use of a general factor of 4 for

97P-0056

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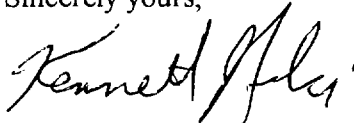
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calculating the caloric value of soluble fibers. Therefore, we would have an objection to the Calorie Control Council advising its members to use a food factor other than that one provided for in the regulations.

Lastly, we do not agree that §130.10 generally allows for standardized foods that require certain amounts of fats or sugars to have the fat or sugar content significantly reduced or eliminated to bear a nutrient content claim. Section 130.10(d)(4) clearly states that an ingredient that is required by the standard must be present in the food at levels that will achieve the technical effect of that ingredient in the food. In cases where it can be demonstrated that reduced levels of the fat or sugar can still achieve the technical effect of the ingredient in the food, the food could be modified in accordance with the requirements of a nutrient content claim.

As you are aware, the Center for Food Safety and Applied Nutrition (CFSAN) has identified in "1999 CFSAN Program Priorities" those areas in which it plans to direct most of its resources during this calendar year. None of the items in your three letters have been identified as priorities for this year. As we identify our priorities for Calendar Year 2000, we will consider whether to add the Council's petitions to our program priorities for 2000. In the meantime, however, to the extent that our priorities and resources permit, we will attempt to respond to your petitions. We are placing a copy of this response and the respective incoming letter in each of the above mentioned dockets on file at Dockets Management Branch. Please contact Gerard L. McCowin, Acting Deputy Director, Office of Food Labeling, 202-205-4561, if you have any questions concerning the petitions.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Kenneth Falci". The signature is fluid and cursive, with the first name "Kenneth" being more legible than the last name "Falci".

Kenneth Falci, Ph.D.  
(Acting) Director  
Office of Food Labeling  
Center for Food Safety  
and Applied Nutrition